DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss our legislative proposals, as well as proposals developed by you and your colleagues on the Committee to enhance FDA's ability to carry out its important public health mission.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies. Recent outbreaks underscored the need to develop multidisciplinary and integrated product safety strategies.

ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN

To address these challenges, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released a Food Protection Plan which provides a framework to identify and counter potential hazards. To achieve the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress.

I would now like to describe some of the highlights of the Food Protection Plan (the Plan) and Action Plan and some recent food safety and food defense activities. The Plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach encompasses three core elements: prevention, intervention and response. The *prevention* element means promoting increased

corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. In these Plans, we identified several new legislative authorities needed to help us fully implement the Plans. As we discuss each subject area, I will briefly summarize those proposed authorities.

MOA with China

Consistent with the goals of the Action Plan, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of food and animal feed products exported from China to the U.S. The MOA establishes a bilateral mechanism to provide greater information to ensure products exported from China to the United States meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress. The first formal bilateral meeting under the MOA between FDA and Chinese regulators was held the week of March 17, 2008, in Beijing.

FDA has also made a commitment to station inspectors and other Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses, (2) identify food vulnerabilities and assess risk, and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

To promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, importers, and other critical components of the food supply chain. For example, in December 2007, FDA released self-assessment tools to minimize the risk of intentional contamination of food and cosmetics. The tools enable industry to get a quick and detailed assessment of the security measures they have in place and to identify areas in which improvements are needed.

FDA requests authority to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on

tanker trucks transporting food. The authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf-life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations would take into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk.

FDA is also seeking explicit authority to require preventive food safety controls for high-risk foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination). Such authority would strengthen FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from these foods.

FDA also requests statutory changes that would require facilities to register every two years and authorize FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

To identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. In order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about sources, spread and prevention of contamination. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

Working with the Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will also continue to work with the Department of Homeland Security on identifying emerging risks and developing rankings so that we can more effectively allocate our available resources to manage these risks.

To enhance the safety of lettuce and leafy greens, FDA is continuing to work with officials in California and with industry to assess the prevalence of factors in and near the field environment which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which Good Agricultural Practices and other preventive controls are being implemented. In the fall of 2007, in cooperation with

industry, state and local governments, and academia, FDA conducted assessments on farms. FDA is also continuing its collaboration with state health and agriculture officials from Florida and Virginia, the produce industry, and several universities to prevent foodborne illness associated with tomatoes from those states. By identifying practices and conditions that can lead to product contamination, FDA and its food safety partners hope to improve guidance and policies intended to minimize the potential for future disease outbreaks.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance, and improve the detection of food system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense. To expand its capacity for the regulation of food and other FDA-regulated products, FDA's Beyond Our Borders Initiative includes increased collaboration with foreign regulators and the use of third parties to provide information about industry's compliance with FDA standards. Legislation to authorize FDA to accredit and use highly qualified independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements for food would be an effective way to further meet the heightened

inspection demand. FDA would not be bound by the information from these third-party organizations in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by FDA when setting inspection and surveillance priorities.

On April 2, 2008, FDA published a notice in the *Federal Register* to solicit public comments on the use of third-party certification programs for foods and feeds, including pet foods. The comment period extends until May 19, 2008. As part of the Agency's response to problems with Chinese aquacultured seafood contaminated with unapproved drugs, FDA worked with the Chinese government to establish a pilot program to demonstrate how aquaculture companies can implement preventive controls that will minimize the risk of unapproved drug residues in the product.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving its ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing agreements with key foreign countries.

As part of the 2009 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet current

Good Manufacturing Practices (cGMPs) or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority. That authority (or an FDA-recognized third party inspector) would certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment to the U.S. FDA would apply this requirement *only* for imported products that have been shown to pose a threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with those of FDA.

As part of the 2009 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA's enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to

issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by FDA for export certificates for drugs and devices.

In addition, while FDA can pursue an inspection warrant or criminal prosecution if it is denied access to inspect facilities here in the U.S., foreign firms can often deny U.S. officials access to their facilities without any adverse consequence. In particular, although FDA can refuse admission of food that appears to be adulterated or misbranded, the Federal Food, Drug, and Cosmetic Act does not explicitly provide for FDA to refuse admission of food if FDA is hampered in making this determination because its efforts to conduct a foreign inspection were unduly delayed, limited, or denied at a facility where the product was manufactured, processed, packed, or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable FDA to keep potentially unsafe food from entering U.S. markets.

FDA can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to "map" or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for emerging food protection problems. FDA microbiologists recently received training from CDC on a new molecular method for rapidly and accurately identifying *Salmonella* serovars. FDA has

purchased the necessary equipment and will be training its field laboratory personnel in upcoming months.

The pet food recalls showed us that we need to also increase our efforts on animal food and feed, as well as human food. To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA is working with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to identify problems with the pet food supply and alert veterinarians and others. FDA also is developing a modernized risk-based Animal Feed Safety System (AFSS) that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals.

To implement a requirement in the Food and Drug Administration Amendments Act of 2007, FDA is developing ingredient, processing, and updated labeling standards for pet food. To assist us in this endeavor, FDA is holding a public meeting on May 13, 2008, to obtain input from stakeholder groups on such standards. At this meeting, we are also asking for input on ingredient and processing standards for animal feed generally.

Response

During the past year and a half, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. While FDA's response to these outbreaks was swift and effective, there is always a need

to respond faster and communicate more effectively with consumers and other partners. During emergencies, important messages must be communicated clearly and through multiple forms of media to consumers and retailers. FDA will enhance its risk communication program through aggressive, targeted campaigns that disseminate clear and effective messages and provide regular updates to help get contaminated products off the retail shelf and out of homes more quickly. FDA has sought expert advice in the field of risk communications from the recently formed Risk Communication Advisory Committee.

To improve our immediate response, FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track-and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. In addition, FDA plans to issue a Request for Applications this year to provide funding to six states to establish Rapid Response Teams to investigate multi-state outbreaks of foodborne illness, perform traceback of implicated foods, and evaluate data from investigations to identify trends.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. Although FDA has the authority to pursue seizure of adulterated or misbranded food through a civil judicial action, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary

actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct an effective recall. In such situations, public health would be best protected if FDA has the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is also seeking a modification to our records access authority that would give FDA more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated *and* presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related* articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors

access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario. The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

We are moving forward to implement the Food Protection Plan and are working with other Federal agencies; state, local, tribal, and foreign governments; as well as with industry to develop the food science and tools necessary to better understand the current risks of the food supply, and develop new detection technologies and improved response systems to rapidly react to food safety threats.

To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA is planning to host a meeting on August 12-14, 2008, with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 states. We also recently established a docket and solicited comments from our stakeholders on the Food Protection Plan and on specific questions related to its implementation. The comment period will remain open until July 31, 2008. We have numerous other outreach activities underway to engage our stakeholders in implementing the Food Protection Plan.

FDA GLOBALIZATION ACT OF 2008

We commend the Members of this Committee and their staff for developing the discussion draft entitled, the "Food and Drug Administration Globalization Act of 2008." We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety and the FDA Food Protection Plan.

We are in the process of reviewing the discussion draft in detail and we look forward to working with you on this legislation. At this time, we can, however, make some general comments that guided the development of the Action Plan for Import Safety and Food Protection Plan, which we believe should also guide the development of product safety legislation.

- Any legislation should allow FDA to set requirements and priorities based on a strong scientific FDA risk assessment.
- Given the breadth and scope of food products imported into the U.S., as well as those produced domestically, FDA cannot rely on inspection as its primary means of ensuring food safety. Any legislation should build on the framework in the Plans: build in safety measures to address risks throughout a product's life cycle and focus efforts on preventing problems first, and then use risk-based interventions to ensure preventive approaches are effective, coupled with a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

- The Federal government should be striving to address food safety concerns while minimizing potential effects on the increasing costs of food.
- While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance and efforts or programs designed to recoup the costs of enforcement actions (such as reinspections), the Administration will carefully review any proposed user fee program to ensure that it is being assessed against identifiable recipients for special benefits derived from Federal activities beyond those received by the general public.
- Any legislation should be carefully designed to avoid creating real or perceived trade barriers.
- Any legislation should empower robust voluntary private sector efforts already underway.

With these in mind, we believe the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections are not primarily focused on high-risk products. Some of these requirements would require such substantial resources that they would not be feasible. Further, such use of resources could detract from more important food safety and food defense priorities.

In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging efforts underway by certification bodies and foreign nations.

Finally, several provisions of this bill may need to be reviewed in light of U.S. agreement obligations, and we are reaching out to the United States Trade Representative for further insight on these.

CONCLUSION

Together, the Food Protection Plan and the Action Plan for Import Safety provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We commend this Committee for its work and look forward to working with Congress to obtain passage of the necessary legislative authorities identified in the Food Protection Plan and the Action Plan for Import Safety. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.